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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------------------|-----------------------------|
| 09/870,144 | 05/30/2001 | Eva Sevick-Muraca | 017575.0680 | 9131 |
| 5073 | 7590 | 06/29/2007 | | |
| BAKER BOTTS L.L.P. 2001 ROSS AVENUE SUITE 600 DALLAS, TX 75201-2980 | | | EXAMINER ROY, BAISAKHI | |
| | | | ART UNIT 3737 | PAPER NUMBER |
| | | | NOTIFICATION DATE 06/29/2007 | DELIVERY MODE ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| | | | |
|------------------------------|------------------------|----------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/870,144 | SEVICK-MURACA ET AL. | |
| | Examiner | Art Unit | |
| | Baisakhi Roy | 3737 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-16 is/are allowed.
- 6) ☒ Claim(s) 17-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>4/20/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments, filed 4/20/07, with respect to claims 1-16 have been fully considered and are persuasive. The rejection of these claims has been withdrawn.
2. Applicant's arguments with respect to claims 17-34 have been fully considered but they are not persuasive. With respect to Sevick-Muraca et al. (5865754), the patented claims anticipate claims 17-34 of this application since claims 1-7, 15-40, and 42-47 are directed to a method of imaging a light scattering tissue by introducing a fluorescent agent into a tissue to enhance imaging performed in accordance with a mathematical expression modeling the behavior of multiply scattered light traveling through the tissue. The fluorescence characteristic is a function of either fluorescence quantum efficiency, fluorescence lifetime, and concentration of the contrast agent. With respect to Perelman et al., ('111), the reference teaches the use of time gated scattered light for locating, imaging, and diagnosing structures within organs. Perelman et al. teach the use of fluorescent exogenous dyes, which provides fluorescent markers with high quantum yields (col. 2 lines 9-19). Therefore Perelman et al. teach determining time-resolved fluorescence emissions to provide accurate information about the position of an object such as a lesion embedded in a tissue and distinguish between tissue types and determining a relationship between degree of image contrast and fluorescence lifetime or yield (col. 9 lines 5-15). Therefore the rejection of claims 17-34 is maintained and repeated below.

Allowable Subject Matter

3. The following is a statement of reasons for the indication of allowable subject matter: Claims 1-16 are allowed. The prior art of record does not teach the use of a contrast agent having a fluorescence lifetime within a factor of about ten of the mean time-of-flight.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 17-34 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7, 15-40, and 42-47 of U.S. Patent No. 5865754. Although the conflicting claims are not identical, they are not

patentably distinct from each other because the patented claims directed to a fluorescence imaging method to generate an image corresponding spatial variation of the fluorescence characteristic of tissue anticipate the current application claims.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 17-34 are rejected under 35 U.S.C. 102(e) as being anticipated by Perelman et al. (6321111). Perelman et al. disclose a method of using time gated scattered light to determine the location and composition of material within various organs or tissues and imaging in three dimensions of the internal structures. The method involves exposing a biological tissue to first and second excitation light and detecting first and second emission from tissue in response to the excitation light (col. 4 lines 42-60, col. 5 lines 61-67), introducing an exogenous fluorescent contrast agent into the tissue after detecting (col. 6 lines 49-52, col. 8 lines 65-67, col. 9 lines 1-7), comparing data corresponding to the first emission with data corresponding to the second emission to evaluate contrast provided by the agent as a function of fluorescence lifetime (col. 6 lines 52-60). The reference teaches using fluorescence to

provide time-of-flight signals with fluorescence lifetimes in the order of a few ns in the range of 0.1 to 10 nanoseconds within a factor of ten of the predetermined time-of-flight (col. 6 lines 61-67, col. 7 lines 1-23). The reference also teaches evaluating the emissions with mathematical expression modeling the behavior of multiply scattered light traveling through the tissue where the mathematical expression corresponds to a diffusion equation approximation of scattered light (col. 9 lines 25- 67, col. 10 lines 1-65, col. 13 lines 39-47). The mathematical expression is in a frequency domain form (col. 3 lines 15-17) and image contrast is provided in terms of phase shift contrast (col. 9 lines 60-61). The reference is also directed to generating an image of the tissue by mapping spatial variation of a level of fluorescence characteristic of the tissue (col. 5 lines 16-20, col. 7 lines 49-65) including determining a modulation amplitude change and a phase change of the light emission relative to the excitation light (col. 3 lines 21-24).

3. Claims 17-34 are rejected under 35 U.S.C. 102(e) as being anticipated by Perelman et al. (6070583). Perelman et al. disclose a method of using time gated scattered light to determine the location and composition of material within various organs or tissues and imaging in three dimensions of the internal structures. The method involves exposing a biological tissue to first and second excitation light and detecting first and second emission from tissue in response to the excitation light (col. 3 lines 13-34, col. 4 lines 22-28), introducing an exogenous fluorescent contrast agent into the tissue after detecting (col. 5 lines 1-16, col. 7 lines 16-32), comparing data corresponding to the first emission with data corresponding to the second emission to evaluate contrast provided by the agent as a function of fluorescence lifetime (col. 5

lines 13-25). The reference teaches using fluorescence to provide time-of-flight signals with fluorescence lifetimes in the order of a few ns in the range of 0.1 to 10 nanoseconds within a factor of ten of the predetermined time-of-flight (col. 5 lines 13-42). The reference also teaches evaluating the emissions with mathematical expression modeling the behavior of multiply scattered light traveling through the tissue where the mathematical expression corresponds to a diffusion equation approximation of scattered light (col. 7 – col. 8, col. 9 lines 12-20). The mathematical expression is in a frequency domain form (fig. 5) and image contrast is provided in terms of phase shift contrast (col. 8 lines 7-45). The reference is also directed to generating an image of the tissue by mapping spatial variation of a level of fluorescence characteristic of the tissue (col. 5 lines 58-67, col. 6 lines 1-8).

Conclusion

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Baisakhi Roy whose telephone number is 571-272-7139. The examiner can normally be reached on M-F (7:30 a.m. - 4p.m.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BR

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